Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Sanofi Pasteur Reports Flu Vaccine Recall for Three Lots of Vaccine from 2014-2015 Season

May 1, 2015 – Sanofi Pasteur has notified CDC and FDA that it is recalling three lots of its Fluzone® Quadrivalent flu vaccine supplied in multidose vials. The lot numbers included in this recall are UI196AA, UI190AC and UI190AD. The recall does not affect other lots of Fluzone® Quadrivalent vaccine in multi-dose vials or any other presentations of Sanofi Pasteur's Fluzone® vaccines. Sanofi Pasteur voluntarily initiated this recall because the vaccine's potency fell below a pre-specified limit prior to the expiration of the vaccine. FDA has established potency standards for flu vaccines in part because when a flu vaccine falls below a pre-specified potency limit, it is possible for the vaccine to provide less than optimal effectiveness. Because of declining flu activity at this time, CDC is not recommending revaccination for people who received the recalled vaccine. The reduced potency of these three lots of Fluzone® Quadrivalent vaccine in multidose vials does not pose a safety concern for people who received this vaccine.

Fluzone® Quadrivalent is a quadrivalent flu vaccine that protects against four influenza (flu) viruses: an influenza A (H1N1) virus, an influenza A (H3N2) virus, and two influenza B viruses (one of the Victoria lineage and one of the Yamagata lineage). For more information, see Types of Influenza Viruses. The issue involves reduced potency in the influenza A (H3N2) and influenza B (Victoria lineage) virus components of the three recalled lots of Fluzone® Quadrivalent flu vaccine supplied in multidose vials. This means these recalled vaccines no longer meet the manufacturer's specifications for potency for these particular viruses. The potency of the remaining influenza A (H1N1) and B Yamagata virus components of this vaccine was within pre-specified limits. Potency (or strength) of a vaccine is determined by the measurement of the concentration of the active ingredient (also called antigen) in the vaccine. Reduced potency does not necessarily mean people vaccinated with this vaccine received reduced benefit, but CDC cannot rule out the possibility.

Given that flu activity in the United States is declining at this time, CDC does not recommend revaccination for people who received the recalled Fluzone® Quadrivalent vaccine in multidose vials. However, people that received the recalled vaccine and have questions or concerns should talk to their doctor. Providers concerned about the potency of the recalled vaccine should contact Sanofi Pasteur Customer Service (number provided below).

People who received the recalled vaccine who are planning to travel to the Southern Hemisphere (where flu season is just beginning) may wish to speak to their doctor about flu treatment or prevention options. Because a new flu vaccine has been formulated for use in the Southern Hemisphere, vaccination with a Northern Hemisphere flu vaccine approved for use in the United States might provide suboptimal protection against flu viruses expected to circulate in the Southern Hemisphere in the coming months. People traveling to the Southern Hemisphere for an extended period of time may wish to consider getting vaccinated with a flu vaccine formulated for the Southern Hemisphere. Southern Hemisphere vaccines are not licensed for use in the United States.

Sanofi Pasteur has sent customers who purchased vaccine from any of the recalled lots instructions to not use the remaining vaccine and it has provided directions for returning unused doses. Additional information on the recalled lots is provided below:

Lot Number:	Expiration Date:	Carton NDCa:	Vial NDC:	Presentation:
UI196AA	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AC	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AD	30JUN15	49281-621-15	49281-621-78	10-dose vials

Further questions should be directed to FDA and Sanofi Pasteur:

- Individuals with additional questions for Sanofi Pasteur can call Sanofi Pasteur Customer Service at 1-800-VACCINE (1-800-822-2463) Monday – Friday, 8:30 AM-6 PM.
- FDA has posted a recall notice on its website (http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/ucm445261.htm).
- Sanofi Pasteur has posted a recall letter to health care providers (https://www.vaccineshoppe.com/assets/pdf/mkt29375-1R_fluzone_qivr.pdf).

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Page last reviewed: May 1, 2015

Page last updated: May 1, 2015

Content source: Centers for Disease Control and Prevention (http://www.cdc.gov/)

SANOFI PASTEUR

IMPORTANT INFORMATION REGARDING THREE LOTS OF SANOFI PASTEUR'S 2014-2015 FLUZONE® QUADRIVALENT (INFLUENZA VACCINE) SUPPLIED IN MULTIDOSE VIALS

April 21, 2015

Dear Health Care Professional:

Sanofi Pasteur is committed to providing our customers with quality vaccines. As part of ongoing monitoring of the stability of all of our influenza vaccines, we have found that the antigen content of 3 lots of the 2014-2015 Fluzone Quadrivalent vaccine supplied in multidose vials has declined below the stability specification limit for 2 strains – A/Texas H3N2 and B/Brisbane (Victoria lineage). Stability tests for the A/California H1N1 and B/Massachusetts (Yamagata lineage) strains in these lots have remained within specification. You are receiving this communication because we have identified that you were shipped doses from 1 or more of these 3 lots.

There are no safety concerns related to these 3 lots and re-immunization is not necessary.

However, in response to the stability testing results, Sanofi Pasteur is initiating a voluntary recall of the remaining doses of 3 lots of Fluzone Quadrivalent vaccine:

Lot Number:	Expiration Date:	Carton NDC[a]:	Vial NDC:	Presentation:
UI196AA	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AC	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AD	30JUN15	49281-621-15	49281-621-78	10-dose vials

This action does not impact any other lot of Fluzone Quadrivalent vaccine or any other presentations of Sanofi Pasteur's Fluzone vaccines.

These lots passed all quality controls and met all licensed specifications required by the US Food and Drug Administration (FDA) at the time of shipping.

If you have any remaining doses from the above lots of Fluzone Quadrivalent vaccine, please do not use them and return the vaccine as outlined in the attached instructions.

We appreciate your attention to this matter.

Sincerely,

David Greenberg

David P. Greenberg, MD
Vice President, Scientific & Medical Affairs and Chief Medical Officer

[a] NDC = National Drug Code.

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